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The ART of Informed Consent: Assessing Patient Perceptions, Behaviors, and Lived Experience of IVF and Embryo Disposition Informed Consent Processes

JODY LYNEÉ MADEIRA*

I. Introduction

[M]any say there is no such thing as informed consent, only consent. “It’s really an art to write a consent form so that a rational person would sign it.”¹

In social science research and medical practice, researchers, scholars, and practitioners regard informed consent as something of a shibboleth. Critics claim consent documents are far from adequate and are drafted at inappropriately high reading levels, that patient recall and comprehension are lacking or “universally poor,”² and that consent practices overwhelm patients with potentially irrelevant information. As some scholars observe, “[m]ost agree that the commonplace ritual of informed consent—focused as it is on the presentation and signing of a consent form—has many flaws.”³ Both patients and physicians suffer as a result; the “iterative, personalized process” of informed consent is rendered

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1. Dr. Henry Greenberg, a cardiologist at Roosevelt–St. Luke’s Hospital *cited in* Lawrence K. Altman, *The Doctor’s World: Fatal Drug Trial Raises Questions About “Informed Consent,”* N.Y. TIMES, Oct. 5, 1993, at B7.

2. Ian N. Olver et al., *Improving Informed Consent to Chemotherapy: A Randomized Controlled Trial of Written Information Versus an Interactive Multimedia CD-ROM*, 74 PATIENT EDUC. & COUNS. 197, 197 (2009).

3. Gil Siegal, Richard J. Bonnie & Paul S. Appelbaum, *Personalized Disclosure by Information-on-Demand: Attending to Patients’ Needs in the Informed Consent Process*, 40 J.L. MED. & ETHICS 359, 360 (2012).

“standardized and inflexible,” and it is still unclear what information is material under various legal standards.⁴ Ultimately, researchers suggest, informed consent has become a “stylized ritual” where patients receive, read (or not), and sign a consent form, where physicians and patients bow to an “ethico-legal decree of uncertain scope” out of defensiveness, habit, or lack of choice, often becoming “cynical about the whole exercise.”⁵

There are efforts afoot, however, to re-envision informed consent, constructing it not as a one-time paper-pushing transaction, but as a dialogic process continuing throughout treatment relationships. From this perspective, conventional informed consent models are incomplete and inaccurate and rely on unrealistic ideals. In the real world, consenting patients are far from the rational autonomous actor, so beloved of bioethics, who chooses according to articulable, well-ordered, and sound individual preferences. In the flesh, patients are far less predictable, make decisions guided by a wide variety of concerns both individualistic and relational, and are even at times irrational.

Informed consent concerns abound in assisted reproductive technology (ART), including in vitro fertilization (IVF), where patients must sign lengthy consent forms for IVF procedures and embryo cryopreservation and disposition, and potentially must complete other forms if they use donor gametes or opt for intra-cytoplasmic sperm injection (ICSI) or preimplantation genetic diagnosis (PGD). Despite vociferous informed consent critiques, however, a literature review revealed no empirical assessments of ART consent forms for infertile patients.⁶ Cahn and Collins are among the few who have deconstructed egg donor consent processes. Although some states, such as Arizona, California, and New York, have imposed informed consent requirements, they observe that “no federal laws regulate the informed consent process,” and that American Society for Reproductive Medicine (ASRM) guidelines lack “enforcement authority apart from excluding noncomplying entities from membership.”⁷ Here, too, Cahn and Collins assert, “the focus is on the physician providing information, rather than ensuring patient understanding.”⁸

4. *Id.*

5. *Id.*

6. See, e.g., Amanda Sillem, Marcelle Cedars, & Heather Huddleston, *Egg Donor Informed Consent Tool (EDICT): Development and Validation of a New Informed Consent Tool for Oocyte Donors*, 99 FERTILITY & STERILITY 1733 (May 2013); Nancy J. Kenney & Michelle L. McGowan, *Looking Back: Egg Donors' Retrospective Evaluations of Their Motivations, Expectations, and Experiences During Their First Donation Cycle*, 93 FERTILITY & STERILITY 455 (2010); Deborah Forman, *Embryo Disposition and Divorce: Why Clinic Consent Forms Are Not the Answer*, 24 J. AM. ACAD. MATRIM. LAW 57 (2011).

7. Naomi Cahn & Jennifer Collins, *Fully Informed Consent for Prospective Egg Donors*, 10 AM. MED. ASS'N J. ETHICS 49, 50–51 (2014).

8. *Id.* at 51.

In the most relevant published article to date, Forman argues that embryo disposition forms may not withstand challenges brought after patients die or divorce. She contends,

[w]hile these documents might appear to settle the matter, . . . the content of the forms and the process and circumstances surrounding their execution raise serious doubts about their value in resolving disputes over embryos in the context of divorce.⁹

Forman suggests that the embryo disposition consent process is imperiled by documents' format and poor drafting, use of technical jargon, patients who are overwhelmed with paperwork and information, the difficulty of considering tragic circumstances such as death and divorce, the disposition decision's extreme difficulty, patients' changing disposition preferences, and "questionable signing circumstances."¹⁰ In fact, she maintains, "strong emotions combined with an excess of information may increase the likelihood of selective perception, by which people screen out information at odds with their preconceived ideas or wants and overemphasize information consistent with them."¹¹

This dearth of empirical research on informed consent in ART is especially odd considering that informed consent practices are clearly a concern within reproductive endocrinology. For procedures such as intrauterine insemination (IUI) and IVF, fertility clinics commonly require patients to attend informational seminars or consultations with physicians or other clinic staff and sign lengthy informed consent packets describing everything from IVF to embryo cryopreservation and disposition. In 2008, the Society for Assisted Reproductive Technologies (SART) even took the time and trouble to devise model consent forms.¹²

This empirical study is the first ever to examine patient consent preferences, behaviors, and experiences. This data is taken from a larger study on treatment decision-making in in vitro fertilization (IVF) conducted by Madeira from 2011 to 2013 that includes 130 patient interviews, over 260 online patient surveys, and ninety interviews with fertility professionals. No patient completed both a survey and interview, and so these populations are distinct. Far from heralding informed consent's imminent demise, this data illustrates its efficacy, with the majority (and in most cases, above 85%) of patients in both populations asserting that they read and understood consent forms.

9. Forman, *supra* note 6, at 59.

10. *Id.* at 67–84, 75.

11. *Id.* at 69.

12. *Id.* at 68, n. 43.

In part I, this article reviews the existing literature on informed consent in clinical research and medical practice, describing both conventional and more recent relational models. In part II, it describes patients' surprisingly positive consent behaviors, including whether they read the entire form, how closely they read it, the forms' comprehensibility, and whether they were surprised by any provisions. It then discusses the legal implications of these positive patient-perception behaviors, and concludes by looking toward a future where informed consent will be supported by new technologies.

II. Informed Consent: The Impossible Dream?

Conventional informed consent definitions focus on "the transmission of standardized information and the signing of documents;" in this model, the doctor gives information to the patient, who considers her possible options and makes a decision.¹³ This conventional definition has been under sustained and furious attack from researchers, who posit that patients do not understand or read consent forms and that forms are difficult to understand.¹⁴ Though practitioners have attempted to improve forms' comprehensibility and organization, these problems apparently persist.¹⁵ Moreover, this conventional definition presumes an individualistic ideal-type patient, a rational and "autonomous moral agent"¹⁶ who makes "sound, competent, thoughtful and rational choices on the basis of information given." This ideal, critics contend, differs radically from the vast majority of real-world patients.¹⁷ Finally, this conventional definition caters more to the interests of providers than patients. Although Beauchamp and Childress refer to five components of consent, including competence, disclosure, understanding, voluntariness, and consent, they lament that "courts and medical literature" have focused almost entirely on disclosure:¹⁸

The legal doctrine of informed consent in the United States has been primarily a requirement of disclosure based on a physician's general obligation to exer-

13. James Olumide Olufowote, *A Dialectical Perspective on Informed Consent to Treatment: An Examination of Radiologists' Dilemmas and Negotiations*, 21 *QUALITATIVE HEALTH* 839, 841 (2011).

14. Natalie Armstrong et al., *Do Informed Consent Documents for Cancer Trials Do What They Should? A Study of Manifest and Latent Functions*, 34 *SOC. HEALTH & ILLNESS* 1230, 1231 (2012).

15. *Id.*

16. Mauth Habiba et al., *Women's Accounts of Consenting to Surgery: Is Consent a Quality Problem?*, 13 *QUALITY & SAFETY IN HEALTH CARE* 422, 422 (2004).

17. C.S. Molyneux, *Trust and Informed Consent: Insights from Community Members on the Kenyan Coast*, 61 *SOC. SCI. & MED.* 1463, 1464 (2005).

18. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 79 (2001).

cise reasonable care by providing information. . . . However, from the moral viewpoint, informed consent has less to do with the liability of professionals as agents of disclosure and more to do with the autonomous choice of patients and subjects.¹⁹

Several scholars have proposed more relational definitions. Katz locates informed consent in the “obligation for conversation,” arguing that, “above all, physicians and patients must learn to converse with one another. . . . requir[ing] that both are also prepared to trust each other.”²⁰ From a relational perspective, the informed consent process is “actualized through oral conversation, facilitate[s] a bond between physician and patient, and allow[s] information to flow more freely between physician and patient.”²¹ Unlike in the conventional definition, there are no “exact rules” governing “successful” informed consent interactions, as the patient’s signature is deprioritized.²² Here, informed consent is not merely information transmission from provider to patient. It is a “mutual and participatory process” that depends in part upon emotions such as “trust and hope.”²³ This helps to explain why individuals can “receive good information, understand it and still have compromised autonomy when factors such as unrealistic optimism influence their decision-making.”²⁴ One study addressing women’s clinical research participation concluded that “the decision to participate was primarily based on their exchanges with the healthcare professionals . . . and appeared to involve a response to socio-emotional aspects of those exchanges rather than their informational content.”²⁵

Indeed, trust may shine even brighter than autonomy as a star at the center of the informed consent galaxy.²⁶ Defined as “judgment and action in conditions of less than perfect information,” trust presumes imperfection, the impossibility of comprehending all aspects of treatment beforehand.²⁷ One effect of a trusting provider-patient relationship is that

19. *Id.* at 81.

20. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* xxi (1984).

21. James Olumide Olufowote, *A Structural Analysis of Informed Consent to Treatment: (Re)productions of Contradictory Sociohistorical Structures in Practitioners’ Interpretive Schemes*, 19 *QUALITATIVE HEALTH RES.* 802, 811 (2009).

22. Howard Brody, *Informed Consent in Primary Care*, 19 *THE HASTINGS CENTER REP.* 5, 7 (1989).

23. *Id.*

24. Joshua Crites & Eric Kodish, *Unrealistic Optimism and the Ethics of Phase I Cancer Research*, 39 *J. MED. ETHICS* 403, 406 (2012).

25. S. Kenyon et al., *Participating in a Trial in a Critical Situation: A Qualitative Study in Pregnancy*, 15 *QUALITY & SAFETY IN HEALTH CARE* 98, 99 (2006).

26. Maiko Watanabe, *For What Am I Participating? The Need for Communication After Receiving Consent from Biobanking Project Participants: Experience in Japan*, 56 *J. HUM. GENETICS* 358, 362 (2011).

27. *Id.*

patients may very well rely on this trust in providers as a proxy for informed consent. But when patients agree to a procedure simply because they trust that their care providers would not do anything to harm them, they render informed consent irrelevant.²⁸

Though most researchers seem to have embraced a more complex and relational informed consent model, medical practice is still caught between these definitions. In contemporary practice, informed consent refers to both “an individual’s autonomous authorization of a medical intervention or of participation in research” and “the social rules of consent in institutions,” what constitutes “an institutionally or legally effective authorization, as determined by prevailing rules.”²⁹ Informed consent fulfills *both* “the moral and ethical purpose” of patient autonomy and choice and “the legal, institutional authorization that a given course of treatment complies with regulations.”³⁰ A consent form can be both contract and prospectus, giving patients information material to decision making and setting forth risks, rights, responsibilities, and grounds for liability.³¹

But it is difficult, if not impossible, for medical practice to both effectively support patient decision making and successfully guard against legal liability. Informed consent’s role in supporting patient decision making may in some or even most instances be confused with and diluted by the need to legally protect medical providers and researchers. Consequently, it is “still seen as bureaucratic legalism rather than as part of patient care.”³² And while the looming threat of litigation reinforces the need to build in professional legal protections, there are no similar clear-cut economic incentives for prioritizing patient-provider dialogue or patient understanding. Therefore, “though the manifest function of the patient information leaflet (PIL) is to satisfy needs in the social world of the patient, it is in reality shaped by its latent function to satisfy needs in the worlds of” medical professionals.³³ Finally, researchers have also faulted informed consent processes for “seeming little more than a ritual.”³⁴

But while we must acknowledge informed consent’s weaknesses, perhaps critics are too hasty in throwing the baby out with the bath water. Ritualistic elements can be boons as well as burdens. Consent interactions

28. Armstrong, *supra* note 14, at 1244.

29. BEAUCHAMP & CHILDRESS, *supra* note 18, at 78.

30. Paul Alexander Clark, *Intensive Care Patients’ Evaluations of the Informed Consent Process*, 26 DIMENSIONS CRITICAL CARE NURSING 207, 207 (2007).

31. Armstrong, *supra* note 14, at 1243.

32. Brody, *supra* note 22, at 5.

33. Armstrong, *supra* note 14, at 1243.

34. Martin H. N. Tattersall, *Examining Informed Consent to Cancer Clinical Trials*, 358 THE LANCET 1742, 1742 (Nov. 24, 2001).

are not “empty,” but are instead “recognisable to patients as . . . sanctioned, consistent with more generalised norms governing quasi-legal transactions,” although patients may feel these routines protect institutions and regard forms as more contractual than informative.³⁵ Consent forms imply that providers and researchers come from credible institutions, are ethical, and comply with practice norms.³⁶ As White and Zimbelman contend, “[b]eing asked for permission to treat has become accepted practice. The judicial tradition supports it; patients expect it, want it, are distraught when it is not forthcoming, and are likely to see its omission as a failure of professionals to respect them.”³⁷ Forms offer control to patients,³⁸ improve treatment efficacy, coping, and satisfaction;³⁹ and can provide patients with an “instruction manual” to which they can refer throughout their treatment.⁴⁰

Moreover, much evidence exists that forms are not the helpful informational aids that policy makers, professionals, and researchers once believed them to be. In a study by Matsui, half of participants did not read the consent form before signing, and yet “many of them felt they understood the proposed research quite well.”⁴¹ Thus, even if consent forms were very easy for patients to understand, “it is not at all clear that they would play the role of supporting rational decision-making for which they are intended”; “[p]atients often describe making their decisions about participation in ways that do not concur with official ideals of ‘good’ decision-making.”⁴² Patients may not read forms or read them closely if they have already had detailed conversations with care providers about a treatment option and written informed consent comes much later. And consent forms are redundant for patients who are resolved to undergo a particular treatment, whatever the forms say.⁴³

While empirical research on informed consent is growing more sophisticated and commonplace, much yet remains to be done. Informed consent research is understandably fraught with multiple tensions; medical professionals and “clinical researchers presumably have an interest in demonstrating that ‘problems’ with the consent process are either nonexistent,

35. Armstrong, *supra* note 14, at 1241.

36. *Id.* at 1243.

37. Becky Cox White & Joel Zimbelman, *Abandoning Informed Consent: An Idea Whose Time Has Not Yet Come*, 23 J. MED. & PHIL. 477, 493 (1998).

38. Habiba et al., *supra* note 16, at 424–25.

39. Olufowote, *supra* note 13, at 802.

40. Armstrong, *supra* note 14, at 1241.

41. Kenji Matsui et al., *Two Methods of Obtaining Informed Consent in a Genetic Epidemiological Study: Effects on Understanding*, 2 J. EMPIRICAL RES. HUM. RES. ETHICS 39, 44 (2007).

42. Armstrong, *supra* note 14, at 1243.

43. *Id.* at 1240.

less serious than thought, or remediable,” whereas ethicists “arguably have an agenda to find issues worthy of thought, debate, and remediation.”⁴⁴ Thus, researchers must “remain objective in the face of widespread acceptance of the tenet that “the process is broken” and that various populations are “at risk” or “vulnerable,” including those deemed to have decisional impairments.”⁴⁵ Attention to patient experiences with informed consent is lacking in just about every area of medical practice. As scholars note

given the central role of consent . . . it remains surprising how little effort has been directed towards exploring patients’ experiences of the process. Little is known about whether the process addresses their needs and the extent to which it fulfils the objectives of signaling partnership and countering paternalism.⁴⁶

III. A Practical Project or an Impossible Dream?

Qualitative and quantitative data drawn from Madeira’s interview and survey patient populations, supplemented with patient commentary, illustrate patient experiences with IVF and embryo disposition consent forms. In both research formats, patients were asked about their perceptions of informed consent’s documentation and dialogic aspects.

In an initial battery of questions, patients were queried about their general attitudes towards informed consent—specifically, whether it was important or bureaucratic, when it began, and who it protected. Of interviewed patients, 40% believed that consent forms protected the doctor, whereas 47% (n=36) felt that the forms protected both doctors and patients; 13% (n=10) were convinced that the forms protected both groups, but that protections were skewed in favor of medical providers. Exactly half of interviewed patients (n=33) perceived that consent forms were important, while 38% (n=25) felt that they were both important and bureaucratic. Only eight patients characterized consent forms as entirely bureaucratic. In responding to a similar question—whether they took the consent form seriously—95% of online survey patients (n=202) replied “yes,” and a mere 5% replied “no.” In addition, 55% of surveyed patients regarded the consent forms as “something to get out of the way,” while 45% did not.

For the vast majority of patients, signing consent documents did not mark the beginning or ending of the informed consent process. A surprising 74% (n=49) of interviewed patients believed the consent process began during their first consultation with the reproductive endocrinolo-

44. Greg A. Sacks et al., *Conducting Empirical Research on Informed Consent*, 25 IRB ETHICS & HUM. RES. S4, S7 (2003).

45. *Id.*

46. Habiba et al., *supra* note 16, at 422.

gist. Only 26% (n=17) felt that it began when documents were first signed. Conversation played a large role in patients' IVF consent interactions; 53% (n=83) of online survey patients found consent conversations more helpful than forms, and 41% (n=63) found them equally helpful while only 6% (n=10) found conversations less helpful.

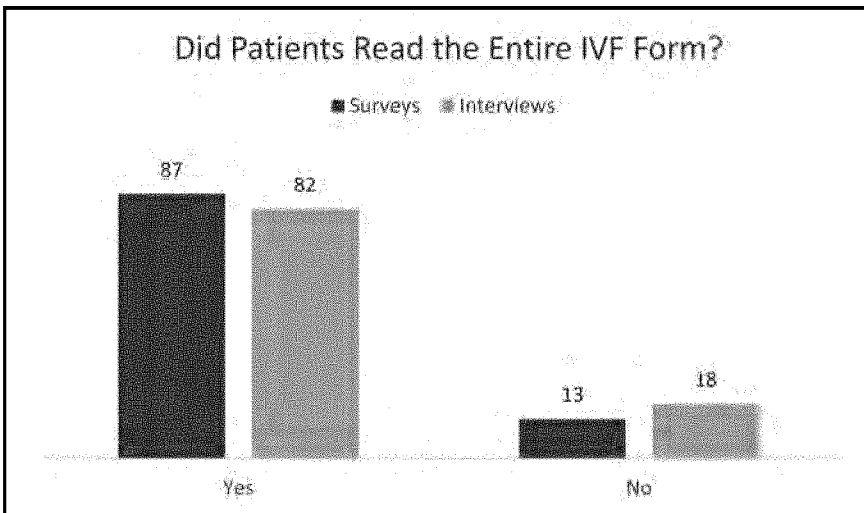
The vast majority of both interview and survey patient populations self-reported that they read and understood IVF and embryo disposition consent forms well. (Note: P = female participant, and H = husband.) As surprising as these conclusions may seem, past studies have also documented high patient self-reports of consent form reading and comprehension. Gammelgaard, for instance, found that in nonemergency cardiovascular trials, 90% of patients said that they had enough information to make a good decision, 80% were aware of the purpose of the trial, and 86% were aware of side effects.⁴⁷

A. Patients' Perceptions of IVF Consent Forms

1. DID PATIENTS READ THE ENTIRE IVF CONSENT FORM?

The vast majority of patients in both survey and interview situations reported reading the entire IVF consent form:

- Yes, I read everything cover to cover. Everything they gave us (P101).
- So I probably read that form, who knows? Fifty times (P104).



47. Anne Gammelgaard et al., *Patients' Perceptions of Informed Consent in Acute Myocardial Infarction Research: A Danish Study*, 58 SOC. SCI. & MED. 2313, 2314 (2004) (citing other studies).

Participant 40 would not have read the form had it been merely legalistic: “[I]t wasn’t all legalese stuff. It was, ‘this is what is going to happen, this is what to expect.’ So I would say we probably read it several times. I actually still have the packet.” Patients often regarded IVF consents as different from other medical consents. “In general . . . at the doctor I just sign whatever they hand me, but in this case I read it pretty thoroughly” (P124). But experienced infertility patients were less likely to read the entire form: “the first time probably yes, [I read it], and the second time because I think I’m a know-it-all and I’d already done it once, I probably skimmed it” (P127).

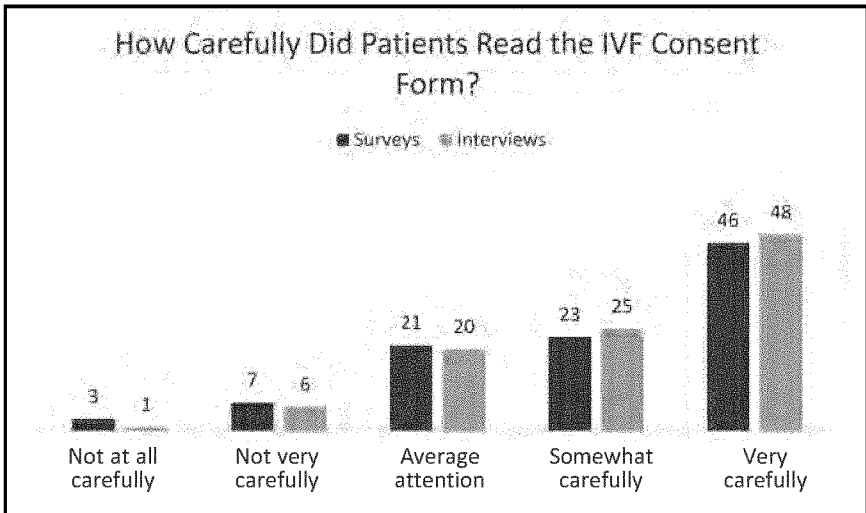
In general, male partners were less likely than their wives to read the entire IVF consent form. “I trusted my wife; . . . she read through everything,” explained Participant M3. A few male partners, however, were more concerned with this form, usually due to their livelihoods. Participant M3 was particularly interested in the form’s legal provisions:

There were some things that I read through completely, and there were some things that I remember I asked [my wife] about, and signed. So like IVF. . . medications. . . . What I read very carefully were the terms and conditions that applied to our business relationship. . . . Because that was something that I could change, and that was something that I needed to understand. I was not going to not sign the form because they didn’t clearly articulate everything about IVF. We knew what we were getting into, and we trusted—again, trust was important there—we trusted that they knew what they were doing.

Patients frequently commented on the length of consent forms, with most feeling “they could probably be condensed” (P29). But not all clinics presented patients with the same consent materials; Participant 73 noticed differences in the consent processes at the different fertility clinics she visited: “My second clinic was not as strict; . . . I still had to sign like a lot of forms, but I could do it at home. I don’t remember them giving me so much detail.”

2. HOW CAREFULLY DID PATIENTS READ THE IVF CONSENT FORM?

The vast majority of patients in both surveys (90%) and interviews (93%) read the form with at least average attention. Again, experienced patients did not read the form as closely: “the first time a 5, the second time, wow, a 2. I kind of was a veteran” (P127). Participants’ remarks illustrate which behaviors were associated with each reading attention level. A “2” (reading “not very carefully”) meant skimming the document: “I did flip through all the pages” (P30). A “3” (reading with “average” attention) meant “I read it like a newspaper article” (P82). A “4” (reading documents “fairly closely”) meant that:



I wasn't reading it like I would read a contract where I was looking for something to trip me up, like if I was reading a [mortgage], I'm looking for anything that's not what I want. . . . I read it very carefully to understand it, but I wasn't trying to make sure they weren't pulling a fast one on us (PM5).

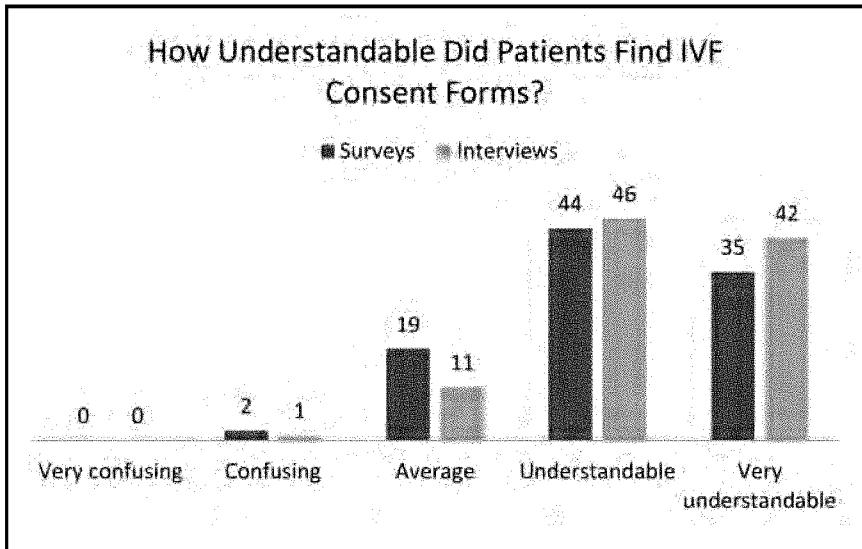
Finally, patients selecting "5" ("very carefully") read with attention to detail: "we had highlights and notes written on the side, so very, very meticulously" (P16).

3. HOW UNDERSTANDABLE DID PATIENTS FIND IVF CONSENT FORMS?

Patient comprehension of IVF consent forms was astoundingly high among both interview (99%) and survey (93%) patient populations describing consent forms as being at least of average comprehensibility.

Patients who found the forms "average" were still comfortable with them: "[they were] understandable enough. It was in medicalized [sic] language but it was clear enough to understand" (P2). Participant 1, who evaluated the forms as "4" ("understandable") attributed her comfort partially to her employment: "in my job I read contracts . . . so I didn't think it was that bad, but maybe other people would." Participant 108 opted for "4" instead of "5" ("very comprehensible") "because of the terminology like 'ICSI' that we weren't familiar with;" Participant 11 also chose "4" noting, "I think the risks aren't properly quantified for people so it's just a laundry list of things that could go wrong, rather than [separating risks into] things that are likely to go wrong versus the things that [are] remotely likely to happen."

Patients who found the forms "very comprehensible" felt that they were "well-written; they didn't use a whole lot of medical jargon that



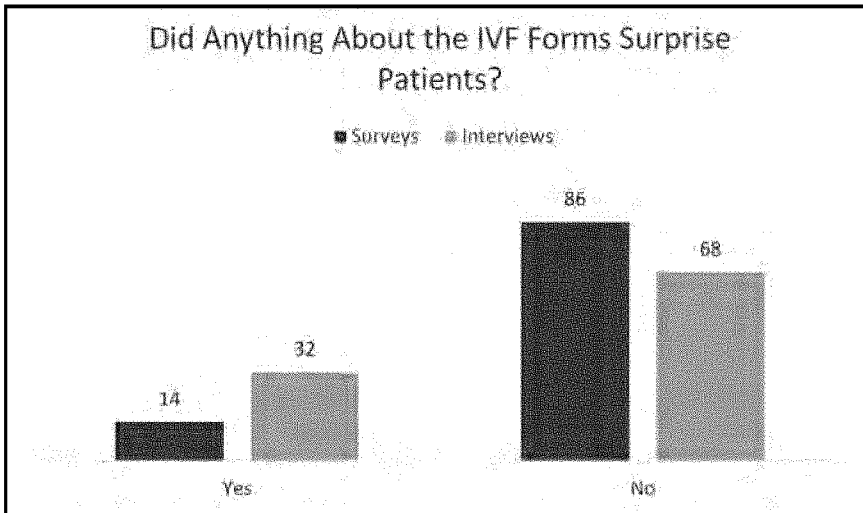
most people wouldn't understand" (P28). These patients frequently mentioned that the best forms did not get "too technical" (Participant 54) so that "human beings could actually read it and understand everything" (P61). In addition, forms were "presented in a logical way, walking you through the process" (P13).

4. DID PATIENTS FIND INFORMATION IN THE IVF CONSENT FORM SURPRISING OR NEW?

Not surprisingly, the majority of patients did not feel that the IVF consent forms presented information that was surprising or new. Interviewed patients were more likely than surveyed patients to be surprised and/or learn new information. Those who did not find the consents surprising often had consulted other sources:

- I had already heard through other people, like in my support group, what to expect (P32).
- I think I had done so much research at that point, nothing was new or different in terms of the process of how it works (P86).
- It "followed really well with what we had gotten in consults" (P75H).

Conversely, patients who were surprised lacked knowledge of IVF to varying degrees: "I had done a lot of research on IUI, but I had not done a lot of research on IVF, because I really didn't think I would ever do it. . . . It was the first time in my whole career of trying to get pregnant that I didn't know what I was walking into until I was given the form and the meeting to explain everything" (P65).



Usually, surprising information was technical, relating to ICSI (injecting sperm into egg), assisted hatching (helping blastocysts to hatch during transfer), selective reduction, medications to be avoided while cycling, egg retrieval surgery, and embryo genetics. Several patients were intrigued to learn exactly how egg retrieval was performed:

- It's just amazing what they can do. I didn't know how they would get them out of me (P52).
- I had assumed that they were going to have her on the operating table, completely cut open, and retrieving them that way, I was not expecting just ok, have her out in what they called like a twilight type of [anesthesia], and inject this, pull this out in like a syringe type of thing. So that was a shock, but for the most part, most of it was self-explanatory. . . . You're sitting here like, "Well wait a minute, you're going to pull an egg out of something like that?" and in my mind I'm thinking eggs that you cook for breakfast (PH50).

But consent forms could also be *too* detailed:

[I]t was a little more detailed on the egg retrieval than I was expecting, because I remember getting a little nauseous when I read it. . . . that's why I'm not a doctor, I'm a lawyer. . . . I got much better, but I don't have that sturdy a stomach (P96).

B. Patients' Perceptions of Embryo Disposition Forms

Signing embryo disposition forms was a very different experience than completing IVF consent documents. Participant 104 thoughtfully distinguished the two types of forms:

I'm thinking of two different things. One is the way [the doctor]'s treating me, the way he's doing procedures on my body. That's one thing. And the other part

of the informed consent was having to do with the embryos. So for me, the embryos was more of my own ethical struggle. Where with [the doctor], yes, I mean, I trusted him to do that; he'd seen thousands of these. So I didn't have a problem with signing anything because I trusted that he knew what he was doing.

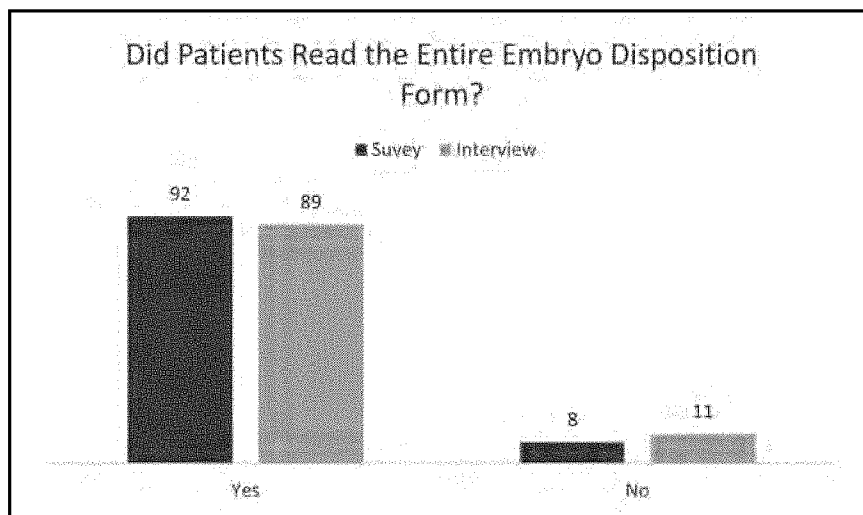
Patients regarded embryo disposition forms as less bureaucratic and more personally relevant. The disposition exercise became an act of personal, or even parental, responsibility.

1. DID PATIENTS READ THE ENTIRE EMBRYO DISPOSITION FORM?

Patients were often taken aback by the embryo disposition form. This was related to whether patients read the entire document. Ninety-two percent of surveyed patients and 89% of interviewed patients self-reported that they had read the entire document. "Of all of it, this was the part that I had not self-educated myself on 'cause I didn't think about it," Participant 72 recalled, "the rest of it, like the whole IVF process, I had already Googled so extensively, and watched TV, and [did] all the research I possibly could, and watched Discovery [Channel] videos on it." The embryo disposition form often took more time and attention to complete than other forms: "I read it . . . several times and I think my husband and I kept going back to it. I think we signed the other parts of the forms first and [went] back to it. To make a decision about it" (P60).

For many patients, making decisions about frozen embryos that did not yet exist, and maybe never would, was surreal—especially if they had never become pregnant and perhaps doubted they ever would:

- I remember discussing it with my partner for about 15 seconds, we signed it

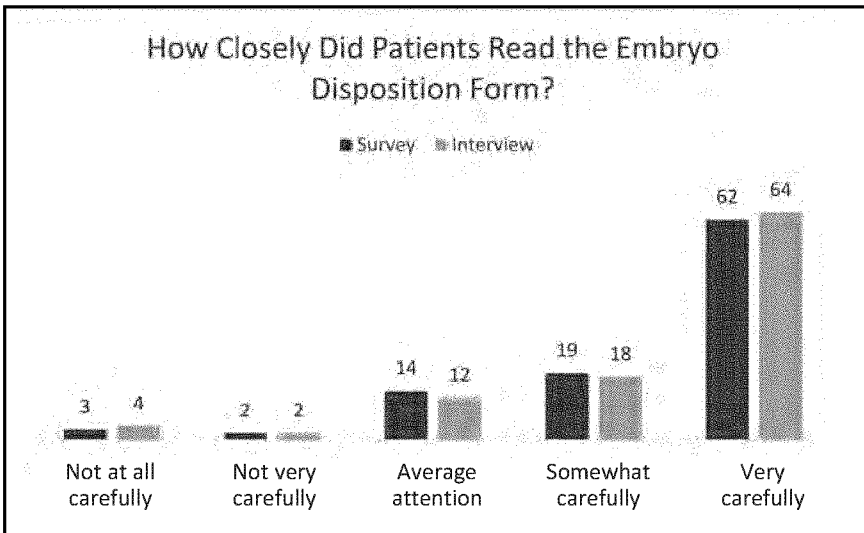


and moved on. . . . We don't feel like, going into a cycle, that . . . it's going to result in divorce or something. Something could happen to one of us, but we're not thinking that far right now. We're thinking about whether or not we can even make an embryo. . . . that's the only thing I can focus on. . . . It seems too far out and it just seems like . . . a distraction right now (P57).

- For the cryo stuff, I remember, I didn't feel odd about it [since it is] a realistic option. But for the frozen embryos, we haven't been there yet, so we haven't emotionally crossed that bridge (H79).

2. HOW CLOSELY DID PATIENTS READ THE EMBRYO DISPOSITION FORM?

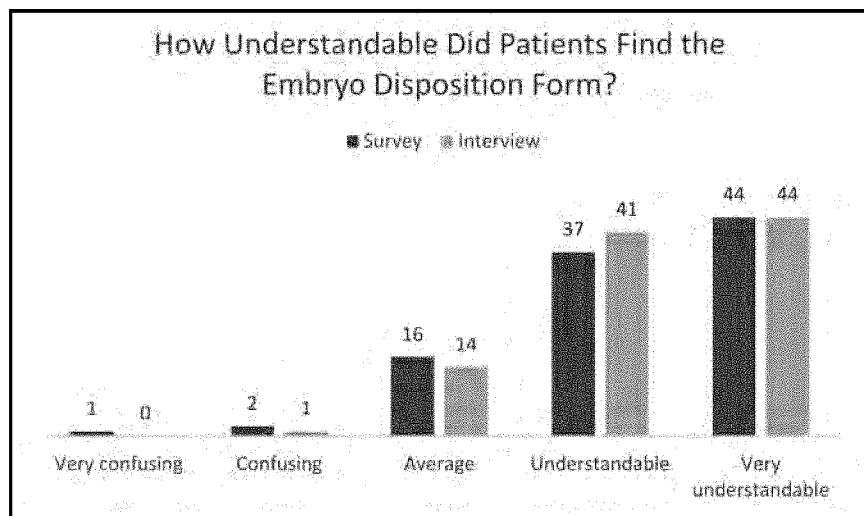
As for the IVF consents, the vast majority of patients from both survey (95%) and interview (94%) populations reported they had read the embryo disposition forms with at least average attention. Here, patients had to make a choice, so at a minimum they had to read descriptions of disposition choices. This form's novelty made many patients read it more closely. Participant 11, who read it "somewhat carefully," opined "that is the most useful form; you make sure you agree on that stuff." Patients were also more likely to closely read forms if they and their partners disagreed over disposition: "We definitely read that at [a] 5, only because we disagreed on certain points" (P19).



3. HOW COMPREHENSIBLE DID PATIENTS FIND THE EMBRYO DISPOSITION FORM?

Notwithstanding the intriguing, potentially novel, and unsettling take of choosing dispositions, most patients in the survey (97%) and interview (99%) populations readily understood disposition forms. "I think it was

black or white, you make one of the following choices. It was more just the idea of what we would do in those situations that made it difficult to fill out” (P26). It was hard for some patients to disentangle form comprehension from the difficulty of disposition choice. One patient noted, “[A]t the time I thought it was somewhat hard to understand. Gosh, maybe it wasn’t necessarily hard to understand. Maybe it was just hard to come to a decision of what to do with the embryos” (P117).

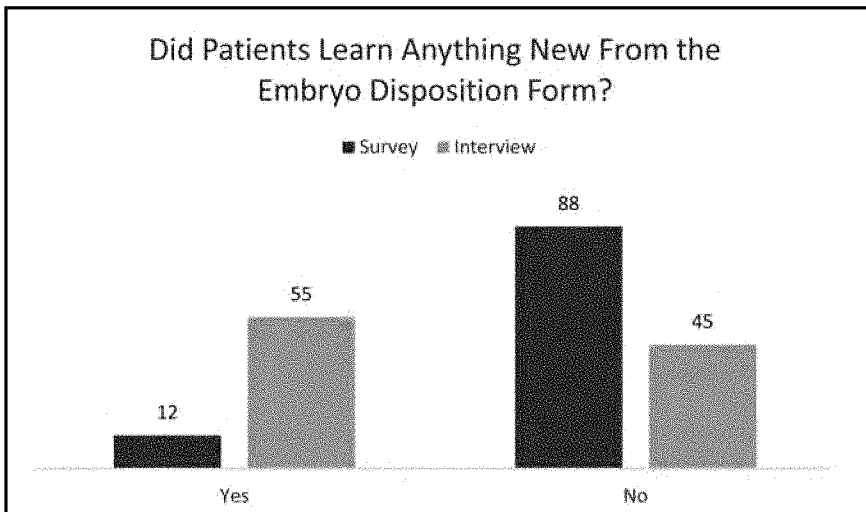
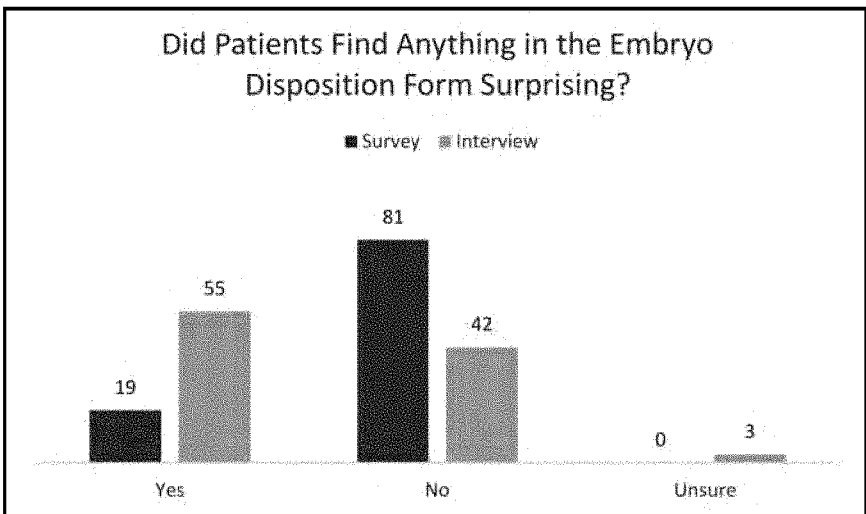


Sometimes patients were confused about particular options. One commented, “there wasn’t a lot of information about [donating to research]; . . . and probably [because of] the fact that they didn’t give a lot of information on that, that was never even an option.” “You start thinking about, “Well, I don’t want them to grow my embryo into a person, a baby, and harvest organs . . . “that’s what I was thinking, worst case scenario . . . how do you know that’s not going to happen?” (P59). Others were perplexed by jargon: “It kind of felt like a lot of legal stuff, like if you abandon the embryos then this will happen. So it wasn’t quite as straightforward as the other one” (P4). Similarly, some patients understood the form but found it too difficult to confront that decision: “I felt sort of excited, . . . we were on our way to going through the procedure. So I didn’t really think a lot about what it meant to have extra embryos or kind of the ethical issues” (P73).

4. DID PATIENTS FIND ANYTHING SURPRISING OR NEW IN THE EMBRYO DISPOSITION FORM?

Again, the idea of having to select embryo dispositions was often shocking to patients:

The one about what to do with the embryos, that stayed with me for a while. . . . That was a year ago and I can still remember, “Wow, you are asking me [] to really sign this.” “Yes, I am giving you permission to destroy the embryos” feels weird, because you’re fighting so hard to get them. . . . Since then of course I have looked into it, like what do people do, who are the people that donate embryos? And why do you make that choice versus another? And then I thought about too, I could sign the consent there that says on the event of something happening to both of us, the embryos would be destroyed. Is this now like organ donation? Do I have to let other people know? “By the way, call the fertility clinic and tell them to destroy our embryos?” Are they going to get a death notice? How does all of that work now? (P30).



As the figures above illustrate, those who were interviewed were more surprised or learned more information from the disposition forms than those who were surveyed—the only significant disparity between these populations. This decision prompted many to humanize the embryos in a way that they may not have done before. Participant 137 felt as if she were making decisions “like they [the embryos] were children.” Patients had a variety of reactions:

- It made you really think of these a[s] real human beings and what would happen if we had leftovers (P60).
- This isn’t just a clump of cells that we’re dealing with . . . there are bigger issues here (P55).
- It was kind of weird that your future children were property already (P54).
- It’s like doing a will; it’s something that you don’t really want to think about (PH134).

Also surprising to patients was the idea of making plans about worst-case scenarios at such a hopeful point in their fertility care. To Participant 25, “it felt really overwhelming to make that decision on the same day that you were just trying to start a process.” Participant 137 almost felt as if signing the disposition form would be acknowledging that her cycle would not be successful: “When I found the one with the freezing, asking me about freezing the eggs [embryos], I wasn’t excited about that because I felt like I wanted that first round to work, so I . . . felt like if I signed that, then I was okay with it not working.” Choosing a disposition option was especially strange for patients who were pessimistic about their conceptive chances: “[I]t seems very clinical, very medical, but this is the possibility of human life. You didn’t have the possibility of human life before the IVF cycle; you just don’t think about it. So now you have to think about this and make a good decision” (P63).

Yet, patients knew that these choices were inevitable: “I know it’s necessary because they have to know what to do with it. I’ve seen TV and stuff where it’s a huge fight, or I’ve read articles where these people have divorced, or they write books about it, and I’m like, ‘Oh, that is nasty—you need those forms’” (P10). Having to make these choices prompted crucial discussions: “[T]hat [form] was actually very helpful because I realized that if we had separated or, God forbid, if one of us passed . . . we actually had different views about what we wanted to do with them. So it made us at least think about it and come to an agreement.” Patients also saw disposition choice as a personal responsibility: “That’s crazy. But it was reality. . . . [we] chose to create these embryos, and we need to be responsible and mature enough to make decisions regarding their future”

(P104).

Several patients found embryo disposition provisions upsetting, particularly embryo destruction: “I know it’s semantics, but the word “destroy” is just really upsetting in that situation” (P30). Participant 111 was upset at the thought of discarding inferior embryos:

If it fertilized but didn’t look right to them, it’d be discarded, and I was horrified by that. I kind of felt like they were saying if it looked like it was developing into a disabled fetus then they would discard it. That was the only thing I was uptight about that I didn’t want to sign. . . . But when I [asked] them, they made me feel like that’s not what it meant at all. I just wanted to make sure they weren’t going to take a living embryo and destroy it. I don’t know if they convinced me that that was not going to happen, but for whatever reason I felt like this is what I need to sign . . . it was probably the one part I had to choke back and sign the paper.

Other patients were unsettled by other disposition form terms. Participant H79 was uncomfortable with the embryo cryopreservation language; his form was “very cold in terms of having to execute these options. If we don’t hear from you, [we’ll] either a) charge your card for the full year, or b) we’re gonna get rid of samples . . . cold, not collaborative, it was a very business[-like] deal.” Several felt it was too early to choose dispositions:

- I was concerned about signing it because I don’t know what’s going to happen . . . is this written in stone? . . . But I still signed it. I don’t even understand why they have you sign that form at that time. I feel like that’s . . . a decision that you have to make down the line. But how can you ask someone to destroy embryos when they don’t even have any embryos and they don’t even know if they’re going to have a successful pregnancy (P67).
- When they say we’re going to do this IVF procedure, and you’re going to be under anesthesia, then I’ll listen to that and say, “Yes I consent to that” because that’s definitely going to happen. But with the embryos, who knows if you get [embryos]? . . . I thought, “That’s so far away and that might not ever happen, why do I need to make a decision about it?” . . . We’re pretty confident that we’re not going to be getting divorced any time soon. It’s just inconceivable. . . . So we checked it off but we didn’t really take it seriously I guess because we knew we’re not getting divorced. So we were like, whatever, it doesn’t matter what we choose (P17).

Finally, many remarked that the embryo disposition forms seemed “really weird” (P124) or gave them a “weird feeling” (P8). Patients negotiated this weirdness in several ways. Some approached the decisions very somberly. “The most difficult document for us to sign w[as] what to do with the embryos should something happen to us or we get divorced or something, because it’s not something that you think about,” Participant 50 emphasized, “It’s just tough and then you kind of have to rationalize it

in your head and talk it out.” Participant 4 and her husband took a more light-hearted approach. “My husband and I were joking about all that stuff. And he was saying that if I died, he’d take the embryos,” Participant 50 recalled, “and I’m like, “What, you’re going to get married again and have my embryos put in some other woman? . . . That’s just crazy!” Others forged a new disposition path; Participant 117 changed the disposition terms to state she and her husband would make a choice if any untoward event occurred: “I think we wrote in that we would determine [disposition] if we were going through a divorce because we didn’t know. . . . we thought, we don’t know if they’ll go for this, but nobody asked a question about it.”

C. Reenvisioning Informed Consent: Reasons for Celebration and Caution

What practical lessons may we take from these research conclusions? First, this new data regarding patients’ IVF informed consent experiences is significant not only because it contradicts commonplace informed consent criticisms, but also because qualitative research methods provide different insights into patient experience than more quantitative methods that usually emphasize patient recall and comprehension. In this study, patients described in their own words how they used consent documents and regarded them as artifacts of treatment relationships.

Second, this data provides empirical evidence that men and women who undergo IVF may be more circumspect than critics believe. It complicates the stereotype of the “desperate” fertility patient,⁴⁸ and helps to decouple desperation from paralysis and incompetence. The essential question is not whether patients are desperate (many are), but how desperation is experienced and how it affects decision-making. Most often, desperation motivates patients to become circumspect, knowledgeable, and active participants in their fertility treatment, not to blindly enroll in endless IVF cycles.⁴⁹

Of course, IVF consent procedures are unique in medical practice. Most patients felt that the consent process began with doctor consultations long before they received the actual consent forms. Most consents are long and detailed, patients usually can take an appropriate time period to read and discuss forms, and the consent process most often includes a face-to-face conversation with a medical professional when patients can

48. See generally Jody Lyneé Madeira, *Woman Scorned: Resurrecting Infertile Women’s Decision-Making Autonomy*, 71 MD. L. REV. 339 (2012).

49. This data comes from a larger study conducted by Madeira on patient emotion and treatment decision making in IVF, with a book manuscript in progress.

ask questions. Moreover, although patients ardently—even desperately—desire a child, on average they are more highly educated and more socioeconomically advantaged than other patient populations.

This empirical evidence that most patients read, understand, and respect IVF consent forms augurs for a presumption that form provisions should be enforced. Optimally (as cautious practitioners no doubt require), a witness or notary public should confirm the identities of patients *and* their partners, and substantiate that both partners have signed the form; this avoids the confusion in *A.Z. v. B.Z.*,⁵⁰ where a husband allegedly signed a blank consent form after which his wife specified that she would receive the embryos upon separation.⁵¹

Moreover, this research illustrates that patients do differentiate between IVF and embryo disposition forms, regarding IVF forms as more bureaucratic and legalistic. This suggests that patients may distinguish consent provisions that (even if informational in nature) are designed to protect clinics from terms geared toward protecting patients, such as disposition provisions. At the same time, however, patients may regard this disposition decision as too premature and therefore irrelevant. Admittedly, the decision to undergo IVF and embryo disposition choice are two different tasks; the former is likely already made at the time of consent, while the latter forces patients to consider possibilities that are novel, personal, difficult, and even quasi-parental.

More empirical research needs to be done to confirm these findings, to test the accuracy of patient self-reports by assessing comprehension and recall, and to further investigate the reciprocal influences of professional-patient relationships and how informed consent processes intersect with patient trust, control, and anxiety. Such research should focus on how patients negotiate one-sided provisions, such as liability waivers, that clearly favor clinics. Patients may very well feel they must accept these terms, although they could regard them as unproblematic because they are commonplace elsewhere in medical treatment and indeed in daily life.⁵² Certain patients are more vigilant about these legalistic provisions, where they may perceive they have more bargaining power, even though they would not wish to renegotiate medical treatment terms. Other components of this same research study illustrate that, though most patients do not seek to change forms, some do attempt to negotiate alterations, and are sometimes successful.

50. *A.Z. v. B.Z.*, 725 N.E.2d 1051 (2000).

51. *Id.* at 1057.

52. See generally MARGARET JANE RADIN, *BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW* (2012).

This study has a number of limitations. This data is based on patients' self-assessments of recall and comprehension. In addition, there is a possible reporting bias towards selecting positive options, such as reading the entire consent form closely and finding it comprehensible. Patients may have felt nervous or ashamed to admit that they did not read the documents, skimmed them, or did not understand them. Other factors, however, mitigate this bias. Surveys were anonymous, and interviewed patients knew they would be assigned a random alias. Moreover, both interview and survey populations readily answered a plethora of other questions about their intimate emotional, psychological, physical, relational, and reproductive lives that are much more invasive than inquiries about consent form perceptions and uses. Finally, most interview participants discussed in detail the many advantages and disadvantages of consent documents and practices, suggesting that they were deeply engaged in informed consent processes. Finally, the fact that survey and interview populations aligned so closely on all but the last question (whether patients were surprised by or learned anything new from embryo disposition forms) indicates that these responses are in fact quite accurate. One may not expect the same reporting bias to affect both the survey and interview populations to the same degree.

IV. Conclusion

In conclusion, this assessment of patients' experiences with IVF and embryo disposition consent forms more closely approximates a qualified informed consent success than an outright informed consent failure. Looking forward, future informed consent practices will grow ever more complex and its assessment more complicated. Inevitably, multimedia applications will soon join documents in the pantheon of informed consent tools. Comparative assessments of these technologies can answer one of the most important, yet uninvestigated, questions in informed consent: are consent documents inextricably linked to bureaucratic institutional interests and litigation protection in American culture, in cultures of practice, and in patients' perceptions so as to render them ineffective as compared to other mediums? After all, "the practice of informed consent as a piece of paper needing a signature is done to protect physicians from law-suits."⁵³ Most likely, as analyses of multimedia informed consent aids in other medical contexts conclude, provider-patient interaction is the bedrock for informed consent, and no tool—text-based or multimedia—can effectively substitute for that interpersonal interaction.

53. Olufowote, *supra* note 13, at 809.